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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,739	12/29/2000	Timothy J. Nichols	P-8863	7216

27581	7590	03/07/2005

MEDTRONIC, INC.
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EXAMINER
COUSO, YON JUNG

ART UNIT	PAPER NUMBER
2625	

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

	Application No.	Applicant(s)
Office Action Summary	09/750,739	NICHOLS ET AL.
	Examiner	Art Unit	
	Yon Couso	2625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2004*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-15* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

1.   Applicant's arguments filed September 14, 2004 have been fully considered but
they are not persuasive.

        a. The objection and the rejection under 35 USC 112 have been withdrawn in
response to the amendment.

        b. The applicant argues that the none of the referenced prior art documents,
alone or in combination, teach or suggest granting, in response to the access request
being associated with the overdrive function, a level of access associated with a
predetermined authorization level. The examiner disagrees. Seeley teaches, in the
paragraphs bridging col 8 and 9, in response to a potential user not being authorized to
have access, the analyzer unit determines whether the potential user is requesting
access associated with an override function. Seeley also discloses pre-registering
access-levels in advance for utilizing that information in the match process (column 7,
lines 37-54). Piosenka et al also discloses utilizing composite data set which may
include data indicating certain privileges or access of the user (column 7, lines 44-50).

2.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed
> or described as set forth in section 102 of this title, if the differences between the
> subject matter sought to be patented and the prior art are such that the subject
> matter as a whole would have been obvious at the time the invention was made
> to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was
> made.

        Claims 1-9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable
over Smith, Jr. et al (U.S. Patent 5,456,692, previously cited, "Smith") in combination

with Piosenka et al (U.S. Patent 4,993,068, previously cited, "Piosenka") and Seeley

(U.S. Patent 6,615,191 B1, newly cited, "Seeley").

In regards to claim 1, Smith discloses a user recognition system (Fig 1) to identify

a user and enable access to instruments associated with at least one implanted medical

device, the system comprising: an implanted medical device (ref no 20, Fig 1, and col

11, line 30) in a patient; a memory associated with the implanted medical device (ref no

40, Fig 1); an instrument (col 11, line 31) in data communications with the implanted

medical device; and an analyzer unit (col 11, lines 40-44) determining whether a

potential user is authorized to have access to the data communications of the

instrument.

Smith does not expressly disclose a sensor unit positioned along the instrument

for generating biometric traits of the user.

However, Smith discloses a user recognition system submitting a password, or

series of passwords, that are known only to field clinical engineers, or others, who are

authorized and have sufficient training to be able to replace the control program (col 11,

lines 40-44).

Piosenka teaches a sensor unit positioned along the instrument for generating

biometric traits of the user (ref no 20-25, Fig 1).

It would have been obvious to one of ordinary skill in the art at the time of the

invention to incorporate Piosenka's sensor unit for generating biometric traits in lieu of

Smith's passwords because it provides a system that is not defeated by extracting

"known" information (e.g. passwords) from the rightful user allowing a fraudulent user to

pose as the rightful user (Piosenka, col 1, lines 51-53, see also first two paragraphs of Summary of the Invention).

Smith and Piosenka do not expressly disclose the analyzer unit wherein, in response to the potential user not being authorized to have access, the analyzer unit determining whether the potential user is requesting access associated with an override function.

Seeley teaches, in the paragraphs bridging col 8 and 9, in response to a potential user not being authorized to have access, the analyzer unit determines whether the potential user is requesting access associated with an override function. Seeley also teaches granting a level of access associated with a predetermined authorization level (column 7, lines 37-54).

Seeley and Smith and Piosenka are combinable because they are from the art of access verification.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Seeley's override function into Smith and Piosenka's system.

The suggestion/motivation would have been to provide access in the case of an injured finger that is not recognized by the match detector (Seeley, col 9, line 3).

Therefore, it would have been obvious to combine Seeley, Smith, and Piosenka to obtain the invention as recited.

In regards to claim 2, Smith further discloses in col 11, line 30, said implanted medical device including a pacer.

In regards to claim 3, Smith further discloses in col 11, line 31, said instrument including a programmer.

In regards to claim 4, Piosenka further discloses in refs no 11-15, Fig 1, said user recognition system including a finger scanner, a camera, and a microphone.

In regards to claim 5, Piosenka further discloses in ref no 13, Fig 1, said biometric traits include a finger scan obtained from said finger scanner.

In regards to claim 6, Piosenka further discloses in ref no 12, Fig 1, said biometric traits include a retina scan obtained via said camera.

In regards to claim 7, Piosenka further discloses in ref no 14, Fig 1, said biometric traits including a voice print obtained from said microphone.

In regards to claim 8, Smith discloses a user authentication system (Fig 3) for identifying and granting access (ref no 301, Fig 3) to at least one user (col 11, lines 40-44) to an implanted medical device (col 11, line 31) in a patient associated with an instrument (ref no 46, Fig 1).

Smith does not expressly disclose the remaining limitations of the claim.

However, Smith discloses the user authentication system submitting a password, or series of passwords, that are known only to field clinical engineers, or others, who are authorized and have sufficient training to be able to replace the control program (col 11, lines 40-44).

Piosenka teaches a biometric-based user authentication system (Fig 1) for identifying and granting access to at least one user associated with an instrument (ref no 1, Fig 1), the authentication system comprising: at least one biometric sensor (ref no

11-15, Fig 1) implemented in the instrument; at least one biometric trait of a user stored

as coded data (col 8, lines 10-32) in a memory bank of said biometric sensor; and

means for analyzing and comparing (col 8, lines 33-68) said at least one biometric trait

with said coded data to grant or deny access.

It would have been obvious to one of ordinary skill in the art at the time of the

invention to incorporate Piosenka's biometric-based user authentication system into

Smith's external programmer 46 because it provides a system that is not defeated by

extracting "known" information (e.g. passwords) from the rightful user allowing a

fraudulent user to pose as the rightful user (Piosenka, col 1, lines 51-53, see also first

two paragraphs of Summary of the Invention).

Smith and Piosenka do not expressly disclose the means for analyzing wherein,

in response to the potential user not being denied access, the analyzing means

determining whether the potential user is requesting access associated with an override

function.

Seeley teaches, in the paragraph bridging col 8 and 9, in response to a potential

user not being authorized to have access, the analyzing means determines whether the

potential user is requesting access associated with an override function. Seeley also

teaches granting a level of access associated with a predetermined authorization level

(column 7, lines 37-54).

Seeley and Smith and Piosenka are combinable because they are from the art of

access verification.

It would have been obvious to one of ordinary skill in the art at the time of the

invention to combine Seeley's override function into Smith and Piosenka's system.

The suggestion/motivation would have been to provide access in the case of an

injured finger that is not recognized by the match detector (Seeley, col 9, line 3).

Therefore, it would have been obvious to combine Seeley, Smith, and Piosenka

to obtain the invention as recited.

In regards to claim 9, Piosenka further discloses in refs no 11-15, Fig 1, said at

least one biometric sensor including a camera, a finger print sensor, and a microphone.

In regards to claim 11, Smith further discloses in col 11, lines 28-44, said means

for analyzing and comparing includes a software system implemented in the memory

bank of the sensor.

In regards to claim 12, Smith further discloses in col 11, lines 44, "replace the

control program", the biometric traits of the user stored as coded data includes

instructions to allow a user with matching traits to have access to a pre-determined set

of data and tools of said implanted medical device.

In regards to claim 13, Smith discloses a method for an identification system of a

user (Fig 3) to provide authorized access (ref no 301, Fig 3) to operational hardware,

software and patient medical data (ref no 301, Fig 3) contained in instruments and

implanted medical devices (col 11, line 31).

Smith does not expressly disclose the remaining limitations of the claim.

Piosenka teaches a method for a biometric-based identification of a user (Fig 1)

to provide authorized access, the method comprising: accepting at least one biometric

trait from a potential user (ref no 11-15, Fig 1, and col 8, lines 33-47); comparing said at least one biometric trait to a stored coded data (col 8, lines 48-68); and granting a qualified access when a match is confirmed between said at least one biometric trait and the stored coded data (col 8, line 67).

Smith and Piosenka do not expressly disclose determining whether the potential user is requesting access associated with an override function.

Seeley teaches, in the paragraphs bridging col 8 and 9, determining whether the potential user is requesting access associated with an override function. Seeley also teaches granting a level of access associated with a predetermined authorization level (column 7, lines 37-54).

Seeley and Smith and Piosenka are combinable because they are from the art of access verification.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Seeley's override function into Smith and Piosenka's system.

The suggestion/motivation would have been to provide access in the case of an injured finger that is not recognized by the match detector (Seeley, col 9, line 3).

Therefore, it would have been obvious to combine Seeley, Smith, and Piosenka to obtain the invention as recited.

3.   Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, Jr. et al (U.S. Patent 5,456,692, "Smith"), Piosenka et al (U.S. Patent 4,993,068, "Piosenka"), and Seeley (U.S. Patent 6,615,191 B1, "Seeley"), as applied to claim 8

above, in further combination with Clayden (U.S. Patent 5,787,185, newly cited,

"Clayden").

In regards to claim 10, Piosenka further discloses said at least one biometric trait

of a user including a fingerprint (ref no 13, Fig 1), a voice print (ref no 14, Fig 1), a

retinal print (ref no 12, Fig 1), a facial model (facial photo, abstract), and a digital

signature (ref no 15, Fig 1).

Smith, Piosenka, and Seeley do not expressly disclose including a veinal imprint.

Clayden teaches biometric identification using veinal imprint (col 2, lines 7-18).

It would have been obvious to one of ordinary skill in the art at the time of the

invention to incorporate Clayden's veinal imprint into Smith, Piosenka, and Seeley's

system because Clayden's method is an improved method of verifying the identity of

individuals (Clayden, col 1, line 33).

4.   Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Smith, Jr. et al (U.S. Patent 5,456,692, "Smith"), Piosenka et al (U.S. Patent

4,993,068, "Piosenka"), and Seeley (U.S. Patent 6,615,191 B1, "Seeley"), as applied to

claim 13 above, in further combination with Freed et al (U.S. Patent 6,132,363, newly

cited, "Freed").

In regards to claim 14, Smith, Piosenka, and Seeley do not expressly disclose

said qualified access including a hierarchical scheme to enable user-specific access

and authorization based on expertise and need.

Freed teaches a qualified access including a hierarchical scheme to enable user-specific access and authorization based on expertise and need (col 12, lines 1-8, and paragraphs bridging col 12-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Freed's teachings into Smith, Piosenka, and Seeley's method because it insures security (Freed, col 11, line 63) and minimizes inadvertent changes to settings that should be factory adjustable only (Freed, col 12, line 7).

In regards to claim 15, Freed further discloses in the paragraphs bridging col 12-13, the hierarchical scheme including distinctions of access to various hardware, software tools to perform therapy, diagnose and monitoring functions designed to provide various levels of authorized access to physicians, nurses, technicians, patients, and their representatives.

5.   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yon Couso whose telephone number is (703) 305-4779. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.
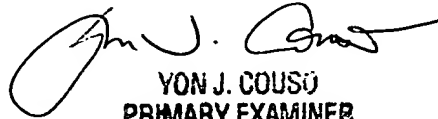
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta, can be reached on (703) 308-5246. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

YJC   YON J. COUSO
                                                          PRIMARY EXAMINER

March 3, 2005